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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09/613,355	07/11/2000	Binie V. Lipps	FWLPAT013US	1325

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John R Casperson
P O Box 2174
Friendswood, TX 77549

EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	

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18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/613,355	Applicant(s) LIPPS ET AL.	
	Examiner Sharon L. Turner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7 and 11-19* is/are pending in the application.

4a) Of the above claim(s) *6,7,11-13 and 15-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,6,7 and 11-19* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1, 6-7, 11-19 are pending.

Information Disclosure Statement

2. The information disclosure statement filed 11-13-00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The references provided were considered as indicated on the attached PTO-1449.

Election/Restriction

3. Applicant's election of Group I, claims 1, 6-7 and 12-14 to the extent of SEQ ID NO:3 in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's assert that claims 1-2, 4-7 and 12-14 are readable on the elected invention of SEQ ID NO:3. However, claims 2 and 4-5 are canceled. Further, claims 6-7 and 12-13 are drawn to a peptide consisting of at least the first five amino acids from the N-terminal of SEQ ID NO:2 and no more than 25 amino acids. While the subject matter of claim 14 is not clearly drawn to elected SEQ ID NO:3, it is presumed that such peptide is within the scope of the claim and thus claim 14 will be examined. However, it is made clear that as claim 14 lacks any discernible structure, the generic claim has only been searched to the extent of elected SEQ ID NO:3. Amendment of the claim to alternative subject

matter would render the claim as being drawn to non-elected subject matter. In conclusion, the subject matter of claims 6-7 and 12-13 are drawn to a non-elected invention. The Examiner deems that only claims 1 and 14 read on the elected invention of SEQ ID NO:3. In particular, the other claims set forth inventions which are not proper species as the subject matter lacks common structure and function, see M.P.E.P. 803.02 which states that:

"Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

Thus, the claims delimit distinct inventions which lack unity and are not proper species. A search of elected SEQ ID NO:3 does not encompass a search for the peptides of claims 6-7 and 12-13. Accordingly, the claims are withdrawn as being directed to non-elected subject matter.

4. Claims 2, 6-7, 11-13 and 15-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 16.

Sequence Requirements and Specification

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

In particular the specification contains various sequences, see in particular at p. 4, line 8, p.5, lines 3-4, p. 6, lines 4-11, p.8, lines 2, 5, and 7 that are not referenced by an appropriate SEQ ID NO: as required.

Claim Objections

6. Claim 1 is objected to because of the following informalities: The claim is written in poor English such that the artisan cannot discern the relationship of the elements. In particular, the claim omits particular articles and/or punctuation that are required for common understanding. Appropriate correction is required. The composition of matter has been examined to the extent that it comprises SEQ ID NO:3.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes various ADESH polypeptide sequences comprising portions of the sequence disclosed at pp. 5, lines 1-6 as AD-5, AD-10 and AD-15, that are disclosed as mimicking the biological properties of NGF. However, the claims recite "A synthetic peptide which produces an antibody which has a binding affinity to NGFs from human body fluids and human origin eukaryotic cells which is higher than a binding affinity exhibited by an antibody produced in immunological response to an NGF derived from venom." While the specification discloses binding affinities of particular antibodies with respect to various specimens as disclosed in Tables II and IV, pp. 11 and 13, the specification fails to disclose the particular sequences used to generate the antibodies of the Tables and further fails to disclose the peptides capable of generating a response which corresponds to the claims.

A genus claim may be supported by a representative number of species as set forth in Regents of the University of California v Eli Lilly & Co, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that

which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

In claims to genetic material, generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material.

Patent does not provide adequate written description of claims generically reciting cDNA encoding vertebrate insulin and mammalian insulin, even though patent discloses rat insulin-encoding cDNA which is species within scope of generic claims, since cDNA is not defined or described by mere name "cDNA," even if accompanied by name of protein that it encodes, and though description of genus of cDNAs may be achieved by means of recitation of representative number of cDNAs, defined by nucleotide sequence, falling within scope of genus, or by recitation of structural features which are common to members of genus and constitute substantial portion of genus, claimed genera of vertebrate and mammal cDNA are not described by general language of patent's written description supported only by specific nucleotide sequence of rat insulin.

Accordingly, a description of a genus may be achieved by means of a recitation of a representative number of genus members falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. However, the instant specification fails to delineate either a representative number of peptides that corresponds to the recitations of the claims or a description of the common structural features of the peptides. Thus, the claimed invention lacks adequate written description support.

9. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000. For example, Jobling et al, Mol. Microbiol., 1991, 5(7):1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce

proteins that differ in native conformation, immunological recognition, binding and toxicity. Thus, the reference exemplifies the importance of conserved structural components to both biological function and immunological recognition. The skilled artisan also recognizes that immunological responses depend upon the structural characteristics (tertiary conformation) of the particular proteins (amino acid sequences) targeted.

The specification describes various ADESH polypeptide sequences comprising portions of the sequence disclosed at pp. 5, lines 1-6 as AD-5, AD-10 and AD-15, that are disclosed as mimicking the biological properties of NGF. However, the claims recite "A synthetic peptide which produces an antibody which has a binding affinity to NGFs from human body fluids and human origin eukaryotic cells which is higher than a binding affinity exhibited by an antibody produced in immunological response to an NGF derived from venom." While the specification discloses binding affinities of particular antibodies with respect to various specimens as disclosed in Tables II and IV, pp. 11 and 13, the specification fails to disclose the particular sequences used to generate the antibodies of the Tables and further fails to disclose the peptides capable of generating a response which corresponds to the claims. Thus, the claim is akin to a single means claim, i.e., where a means recitation does not appear in combination with another recited element of means. In the instant case, the claim recites a synthetic peptide as an element of means. However, the element of means is described only by it's properties and not by it's structure. While the specification discloses AD-5, AD-10 and AD-15, the disclosure falls short of teaching that such peptides exhibit the properties recited in claim 14.

Moreover, the specification fails to teach particular peptides which correspond to the properties as recited in claim 14. There is no description of any structural molecule which produces an antibody which has a binding affinity to NGFs from human body fluids and human origin eukaryotic cells which is higher than a binding affinity exhibited by an antibody produced in immunological response to an NGF derived from venom. Thus, it seems that the claim is subject to an undue breadth rejection under 35 USC 112, first paragraph. In particular MPEP 2164.08(a) and In re Hyatt, 708F.2d 712, 714, 715 (218 USPQ 195, 197) (Fed. Cir. 1983) describe where a single means claim which covered every conceivable means for achieving the stated purpose was held non-enabling for the scope of the claim because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

The specification does not enable the broad scope of the claims which encompasses a multitude of analogs or equivalents because the specification does not teach which residues can or should be modified such that the polypeptides retain sufficient structural similarity to produce antibodies as claimed. The specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful and the skilled artisan would not expect functional conservation among homologous sequences and the ability of the artisan to determine such is unpredictable as set forth above. Thus, applicants have not provided sufficient

guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, for the aforementioned reasons the artisan can not make and use the invention claimed.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 1 lacks particular modifiers, punctuation and/or articles such that the artisan can discern the compositional matter claimed. The claim further recites comprising followed by consisting of and thus the metes and bounds of the claim with respect to SEQ ID NO:3 are indefinite. The subject matter is presumed to be to a peptide comprising SEQ ID NO:3 consistent with the broadest reasonable interpretation of the claim.

12. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 14 recites NGFs. NGF is recognized in the art as nerve growth factor. However NGFs is not apparently recognized in the literature

as a compound. Clarification of the term is required. If the term is merely intended to be plural or possessive such should be clearly indicated within the claim using appropriate language or punctuation.

Status of Claims

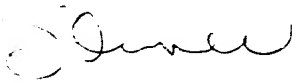
13. No claims are allowed.

14. A synthetic peptide comprising or consisting of SEQ ID NO:3 is free of the prior art.

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.



Sharon L. Turner, Ph.D.
December 24, 2002